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07/782,696

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/782,696 10/25/91 CHUTER

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7-1217-1
EXAMINER

BRITTINGHAM, D

ART UNIT	PAPER NUMBER
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3308
DATE MAILED:

07/01/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined ☒ Responsive to communication filed on 3-18-92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. (2/2/92: 4/8/93) 4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474. 6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1,2,5,9-11,16,17,20 and 24-40 are pending in the application.
- Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 3,4,6-8,12-15,18,19,21-23 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1,2,5,9-11,16,17,20 and 24-40 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24 and 27 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Choudhury.

With respect to claim 24, Choudhury discloses a graft comprising a spring assembly (see column 2, lines 40-44 and figures 3 and 4), introducer means (see column 2, line 67 - column 3, line 11) and retaining means (see column 2, lines 45-56 and column 3, line 14 - column 4, line 4).

With respect to claim 27, see column 2, lines 45-56 and column 3, line 14 - column 4, line 4.)

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 1, 2, 5, 9-11, 16-17, 20, 25, 26 and 28-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Choudhury in view of Kreamer.

With respect to claims 1, 20, 25, 28, 29, 30, 39 and 40, Choudhury discloses a radially expandable graft comprising a spring expanding assembly (see column 2, lines 40-44), anchoring means (see figure 4, element 28), a tubular carrier (see column 2, lines 45-49), a central control means (see figure 1, element 38), mooring loops (see column 2, lines 52-56) and disposable ties for introducing the graft (see column 2, line 67 - column 3, line 17). Kreamer teaches using a removable sheath for introducing the graft in order to protect the blood vessel from the graft. (See column 6, lines 45-54.) It would have been obvious to one of ordinary skill in the art to have replaced the ties of Choudhury with the removable sheath of Kreamer in order to protect the blood vessel from the graft.

With respect to claim 2, see Kreamer column 4, lines 56-64.

With respect to claim 5, see Choudhury figures 3 and 4.

With respect to claims 9 and 10, see Choudhury figure 4.

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With respect to claim 11, see Choudhury figure 4, element 28.

With respect to claim 16, see Kreamer column 4, lines 34-37.

With respect to claim 17, see Kreamer column 4, lines 6-10.

With respect to claim 26, Choudhury discloses a retaining means comprising an elongated member with a head which facilitates movement of the graft, but which does not expand. (See column 2, lines 45-49.) Kreamer teaches using an elongated member having an expandable head for occluding the blood vessel. (See column 2, lines 53-60 and figure 9.) It would have been obvious to one of ordinary skill in the art to have replaced the head of the Choudhury device with the expandable head of Kreamer in order to occlude the blood vessel and minimize blood flow through the surgical site.

With respect to claims 31 and 32, Choudhury discloses a radially expandable graft comprising a spring expanding assembly (see column 2, lines 40-44), anchoring means (see figure 4, element 28), a tubular carrier (see column 2, lines 45-49), a central control means (see figure 1, element 38), mooring loops (see column 2, lines 52-56) and disposable ties for introducing

the graft (see column 2, line 67 - column 3, line 17). Kreamer teaches using a removable sheath for introducing the graft in order to protect the blood vessel from the graft. (See column 6, lines 45-54.) It would have been obvious to one of ordinary skill in the art to have replaced the ties of Choudhury with the removable sheath of Kreamer in order to protect the blood vessel from the graft.

Kreamer also teaches to use short spikes, which attach to the prosthesis at a position remote from the proximal end, for securing the graft while the sheath is being removed. (See figure 8, element 78 and column 6, lines 39-66.) It would have been obvious to one of ordinary skill in the art to have included the short spikes on Choudhury in order to secure the graft while the retaining means are removed.

With respect to claim 33, Kreamer teaches using an elongated member having an expandable head for occluding the blood vessel. (See column 2, lines 53-60 and figure 9.) It would have been obvious to one of ordinary skill in the art to have replaced the head of the Choudhury device with the expandable head of Kreamer in order to occlude the blood vessel and minimize blood flow through the surgical site.

With respect to claim 34, see Kreamer column 6, lines 51-66.

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With respect to claim 35, see Kreamer column 6, lines 59-66 and figure 8, element 8.

With respect to claim 36, see Choudhury column 2, line 67 - column 3, line 17.

With respect to claim 37, see Choudhury figure 4.

With respect to claim 38, see Kreamer figure 9 and column 2, lines 53-60.

Applicant's arguments filed 18 March 1993 have been fully considered but they are not deemed to be persuasive.

With respect to Applicant's arguments regarding Examiner's use of Choudhury, Examiner disagrees. Once the slip rings are removed from the Choudhury device, the spring self expands without balloons, etc. Therefore, self expansion of the Choudhury device is inherent in the design of the stent.

With respect to Applicant's arguments regarding Examiner's use of the Kreamer reference, Examiner disagrees. Examiner used Kreamer to show a teaching of using a removable sheath for protection of the vessel while introducing the graft. At the bottom of page 11 and top of page 12, Applicant states: "Clearly, the Kreamer reference teaches use of an outer sheath positioned around the graft to protect the contact adhesive positioned on the outer surface of the vessel wall during

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insertion thereof." Examiner agrees with this statement and this, in fact, provided the motivation for Examiner's combining Choudhury with Kreamer. Applicant further states: "The Kreamer reference does not disclose, teach, or even suggest using the outer sheath to maintain the inflation balloons of the Kreamer apparatus or the expansion rings of the Choudhury reference in a compressed state as claimed in applicant's invention." Examiner is only required to find structure and a motivation for combining references if two or more references are combined; Examiner is not required to find a motivation identical to that as claimed by Applicant.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication should be directed to Debra S. Brittingham at telephone number (703) 308-0858.



D.S. Brittingham
June 23, 1993



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